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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,355	07/30/2003	Carsten Momma	117163.00077	9258
21324	7590	06/08/2005	EXAMINER	
HAHN LOESER & PARKS, LLP One GOJO Plaza Suite 300 AKRON, OH 44311-1076			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5A

<b>Office Action Summary</b>	Application No. 10/630,355	Applicant(s) MOMMA ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 16-25, 30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 26-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/21/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I and Species A in the reply filed on 4/4/05 is acknowledged. The traversal is on the ground(s) that the product can be made of a different material other than metal. This is not found persuasive because this supports the Examiner's position that the methods of making would be different since the method of making clearly sets forth that the medical device is made of metal. The restriction establishes that the claimed product does not require it to be made of metal, thus the methods of making would clearly be different and the restriction is proper. Additionally, since the Applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case, the species restriction is proper.

Claims 16-25,30,31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The

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abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and *concise* and should not repeat information given in the title. It *should avoid using phrases which can be implied*, such as, "**The invention concerns**," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the use of implied and redundant language. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,5-13,26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (6254632). Wu et al. disclose ( Fig. 2B) a stent having a base body with a plurality (col. 8, lines 50-56) of microdevices **200** that are raised out to form a microcannula **218** on the outer surface to penetrate into the vessel wall, col. 6, lines 13-17. Wu also discloses the diameter and length of the microcannulae can be 100µm for both dimensions, col. 11, lines 63-66. Fig. 4A shows a cover layer **420** of biodegradable material (col. 6, lines 33-42) that closes the active substance **410** in the deposit. The microdevices are fully capable of being applied using hybrid technology. Wu additionally discloses the active substance is liberated once the stent is implanted and the microcannulae engage the vessel wall, col. 6, lines 18-26. Wu discloses the

stent can be made from a biodegradable material and from a magnesium alloy, col. 4, lines 43,44,47,48,54.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3,4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. '632. Wu et al. is explained supra. Wu does disclose the lengths or depths of the microcannulae can be any dimension depending on the amount of drug desires to be delivered, col. 6, lines 61-66. However, Wu fails to disclose the lengths of the microcannulae to be 180 $\mu$ m-250 $\mu$ m. It would have been an obvious matter of design choice to modify the length of the microcannulae, since applicant has not disclosed that using a length of 150 $\mu$ m or 180 $\mu$ m provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the length taught by Wu et al. or the claimed lengths in claim(s) 3,4 because both stents perform the same function of delivering a therapeutic substance to a vessel and anchoring the stent in the wall.

Claims 14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. '632 in view of Hossainy et al. (6287628). Wu et al. is explained supra. However, Wu fails to disclose the use of a biodegradable drug carrier to hold the active

substance. Hossainy et al. teach that impregnated polymers can be used to hold therapeutic materials to place in the microcannulae (col. 9, lines 21-25) and that biodegradable carriers can be used, col. 10, lines 50-52, 57-59. It would have been obvious to one of ordinary skill in the art to use a biodegradable carrier to hold the drug and fill the microcannulae as taught by Hossainy in the stent of Wu et al. such that it degrades over time and has a controlled release rate at the implantation site.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).